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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,719	06/27/2003	Likan Liang	02-850-CIP	9414
	7590	11/23/2005	EXAMINER	
Raj Bawa Shire Laboratories, Inc. 1550 East Gude Drive Rockville, MD 20850			TRAN, SUSAN T	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 11/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Supplemental  
Notice of Allowability**

Application No.

10/607,719

Examiner

Susan T. Tran

Applicant(s)

LIANG ET AL.

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1615

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Response filed 10/21/05.
2. ☒ The allowed claim(s) is/are 19,23,24,26,27 and 29-42.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date 11/15/05.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_



### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Paul M. Booth on 11/15/05.

The application has been amended as follows:

In the specification, at page 31, line 11, the phrase "stabilizer is between 0 W/W% and 30 W/W%" has been amended to "stabilizer is between about 0 W/W% and about 30 W/W%".

Claim 19, line 20, at the end of the claim, the second punctuation "." has been deleted.

Claim 19, last line, after the phrase "and no crystallization of fibrates is observed for at least 24 hours", the phrase ", wherein the amount of said solubilizer is between about 20% to about 80% by weight of the formulation, and wherein the amount of said stabilizer is up to about 30% by weight of the formulation" has been inserted.

Claims 25 and 28 have been canceled.

Claim 26, line 4, after the term "polyethylene glycol monoethers", the second punctuation "," has been deleted.

Claim 26, last line, the term "or" has been deleted.

Claim 37, line 7, before the phrase "one or more fibrates solubilizers" the phrase "about 20% to about 80%" has been inserted.

Claim 37, line 11, before the phrase "one or more stabilizers" the phrase "up to about 30%" has been inserted.

Claim 40, line 4, the term "optionally" has been deleted.

Claim 40, last line, the phrase "the stabilizer is between 0 W/W % and 30 W/W %" has been amended to "the stabilizer is between about 0 W/W % and about 30 W/W %".

Claim 40, at the end of the claim, the limitation "and the stabilizer is present in an amount sufficient to prevent the crystal growth of the fibrates" has been inserted.

Claim 41 has been amended as follow: -- "A method according to claim 40, wherein said formulation has a  $C_{max}$  that is at least 1.2 times that of Lipanthyl<sup>®</sup> or TriCor<sup>®</sup> or the AUC<sub>0-</sub> is at least 1.5 times that of Lipanthyl<sup>®</sup> or TriCor<sup>®</sup> when administered to mammals in the fasted state". --

Claim 42 has been amended as follow: -- "A method according to claim 41, wherein said formulation has a saturation factor of between about 1.05 and 2.5." --

The following is an examiner's statement of reasons for allowance:

The reason for allowance of the claims is the N-alkyl derivative of 2-pyrrolidone as a solubilizer, and surfactant, as well as the limitation stabilizer to prevent crystal growth of the fibrates, into all independent claims. The cited reference does not teach a

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method for the treatment of endogenous condition consisting essentially of an improved bioavailability oral formulation consisting essentially of combination of the claimed solubilizer, stabilizer, and surfactant with a fibrate. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

A handwritten signature in black ink, appearing to read 'S. Tran', with a long, sweeping horizontal line extending to the right.

S. Tran  
Patent Examiner  
AU 1615